OCT-16-03 14:43 From: MCDONNELL BOEHNEN HULBERT & BERGHOFF

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Remarks

Applicants thank the Examiner for granting an Interview on October 15, 2003 in

the above-mentioned case. Applicants firstly note that the amendment to claim 15,

which changed the amino acid positions of the variant from 4 and/or 5 to 3 and/or 4, had

indeed already been made in the Response mailed on October 7, 2002. A copy of the

claims, as pending, is shown on pages 2-4 of this communication. The only amendment

made to the claims herein is the cancellation of withdrawn claims 116-117. Claims 6, 27,

34, 41, and 43 have been allowed, only claims 8, 15, and 21 remain rejected.

Applicants incorporate their remarks from the response after final, mailed July 21,

2003, herein. This paper represents a written statement recording the substance of the

October 15, 2003 interview (see MPEP §713.04).

Rejection of Claims 8, 15, and 21 Under 35 U.S.C. §112, first paragraph

Claims 8, 15, and 21 stand rejected under 35 U.S.C. §112, first paragraph as

allegedly lacking enablement. Applicants respectfully traverse the rejection.

The Examiner has asserted that the claimed variants of SEQ ID NO:4 and SEQ ID

NO:5 may not be enabled because the specification allegedly does not demonstrate that

the claimed specific binding proteins retain binding to variants of SEQ ID NO:4 and SEQ

ID NO:5.

The specification, however, teaches that the claimed specific binding proteins

specifically bind to a core sequence, SEQ ID NO:1, and in particular, bind to SEQ ID

NO:4 and SEQ ID NO:5. See specification, page 36, lines 9-19 (teaching that

monoclonal antibody 8H.8 specifically binds to SEQ ID NOs:4 and 5); page 28, lines 6-

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18 (teaching that SEQ ID NOs:4 and 5 inhibited 8H.8 from competitive binding to native and recombinant canine IgE). The specification also teaches that the amino acids at positions 2 and/or 3 of SEQ ID NO:1, positions 3 and/or 4 of SEQ ID NO:4, and positions 5 and/or 6 of SEQ ID NO:5 can be any amino acid. See specification page 10, line 16 through page 11, line 18. The core sequence of SEQ ID NO:1 is aligned with SEQ ID NOs:4 and 5 below:

SEQ ID NO:1

Leu-Xaa-Xaa-Tyr-Arg

SEQ ID NO:4

Thr-Leu-Leu-Glu-Tyr-Arg-Met

SEQ ID NO:5

Gly-Met-Asn-Leu-Thr-Trp-Tyr-Arg-Glu-Ser-Lys

In particular, the specification teaches that the 8H.8 monoclonal antibody, which was derived using the C-terminal 71 amino acids of the full length exon 3 of canine IgE, specifically binds to a polypeptide of SEQ ID NO:4, SEQ ID NO:5, and the whole canine IgE protein. See specification at page 24, lines 13-20; page 28, lines 6-18. The specification also teaches that the 8H.8 monoclonal antibody does not bind to peptides that do not retain the Leu-Xaa-Xaa-Tyr-Arg (SEQ ID NO:1) core sequence. See specification page 36, lines 1-19. Therefore, the specification teaches that the Leu-Xaa-Xaa-Tyr-Arg core sequence must be retained and that the amino acids at position 2, 3, or both 2 and 3 of the core sequence can be substituted with any amino acid. SEQ ID NO:4 and 5 retain the core sequence of SEQ ID NO:1 and demonstrate that positions 2, 3, or 2 and 3 of the core sequence can be substituted with any amino acid.

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The specification also provides routine assays that can be used to determine if a claimed specific binding protein of the invention specifically binds a variant peptide. See Example 2.

Therefore, one of skill in the art could make and use a specific binding protein that binds to a polypeptide shown in SEQ ID NO:4, SEQ ID NO:5, or the recited variants of SEQ ID NO:4 and SEQ ID NO:5. As such the claims 8, 15, and 21 are enabled by the specification. Applicants respectfully request withdrawal of the rejection.

Respectfully submitted,

Date: Oct 16,2003

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